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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,386	07/19/2000	BERND FABRY	H-3190-PCT/U	2052

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COGNIS CORPORATION
PATENT DEPARTMENT
300 BROOKSIDE AVENUE
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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,386

Applicant(s)

FABRY, BERND

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Non-Final Office Action

Claims 11-30 are pending. No claim is allowed. All previous rejections are withdrawn.

The presently claimed invention is drawn to a method of reducing serum cholesterol content in a mammal said method comprising:

- (i) Providing a hypocholesteremic preparation comprising at least one phytostenol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms; and
- (ii) Administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.

The cited prior art will show that the instant invention is *prima facie* obvious and that one skilled in the art would have been motivated to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-30 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Page 2 of the Specification states: "The invention provides the use of esters of phytostenols with fatty acids having 6 to 24 carbon atoms and **at least two conjugated double bonds**, optionally together with potentiating agents selected from the group consisting of tocopherols, chitosans, phytostenol sulfates and/or (deoxyribonucleic acids for producing hypocholesteremic preparations."

The term "at least" is not in the claims. This is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-30 are rejected under 35 U.S.C. 102(e) as being anticipated by claims 11-29 of WEITKEMPER et al¹. WEITKEMPER et al discloses a process for reducing serum cholesterol levels in warm-blooded organisms comprising administering an effective amount of a hypocholesterolemic composition to the warm-blooded organism, the hypocholesterolemic composition containing: (a) an active ingredient selected from the group consisting of a phytosterol, a phytosterol ester, and mixtures thereof; and (b) a potentiating agent selected from the group consisting of a chitosan, a (deoxy)ribonucleic acid, and mixtures thereof.

The instant claims differ from the reference in claiming the *method* of reducing serum cholesterol, while the reference discloses a *process* by the same composition. The instant invention is anticipated by the reference.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

¹ United States Patent No. 6,444,659 B1. See the entire document.

Claim Rejections - 35 USC § 103 – First Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as obvious over WESTSTRATE et al², in view of KOBATAKE et al.

WESTRATE et al teaches, "A margarine with sterol-esters from soybean oil, mainly esters from sitosterol, campesterol and stigmasterol, is as effective as a margarine with sitostanol-ester in lowering blood total- and LDL-cholesterol levels without affecting HDL-cholesterol

² Examiner notes that the publication date listed in the journal entry is "1998", so the Examiner has included the abstract of this article, which lists the publication date as "May 1998". See the entire document.

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concentrations. Incorporation in edible fat containing products of such substances may substantially reduce the risk of cardiovascular disease in the population.”³

In the very first sentence of the reference, WESTRATE et al teaches the current state of the art (as of May 1998): “It is well established that linoleic acid lowers blood cholesterol concentrations compared to other more saturated types of fatty acids or carbohydrates.” The Examiner notes that the Applicants used lineolic acid in their examples.

KOBATAKE et al teaches, “Serum total cholesterol level was significantly lower only in the animals fed on DHA, whereas serum triglyceride concentration was significantly lower only in the animals fed on EPA.”

Instant claims differ from the prior art in claiming a broader scope of conjugated fatty acids.

One skilled in the art would have been motivated to prepare a method of reducing serum cholesterol content in a mammal said method comprising providing a hypocholesteremic preparation comprising at least one phytostenol ester of a conjugated fatty acid because the prior art of KOBATAKE et al and WESTRATE et al teach that EPA and DHA lower serum cholesterol levels and that esters from sitosterol, campesterol and stigmasterol is as effective as a margarine with sitostanol-ester in lowering blood total- and LDL-cholesterol levels. WESTRATE et al specifically teaches that it is well established that linoleic acid lowers blood cholesterol concentrations compared to other more saturated types of fatty acids or carbohydrates.

³ See *Conclusion* on p334.

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103 – Second Rejection

Claims 11-30 are rejected under 35 U.S.C. 103(a) as obvious over WESTSTRATE et al, in view of KANTHA.

WESTRATE et al teaches, "A margarine with sterol-esters from soybean oil, mainly esters from sitosterol, campesterol and stigmasterol, is as effective as a margarine with sitostanol-ester in lowering blood total- and LDL-cholesterol levels without affecting HDL-cholesterol concentrations. Incorporation in edible fat containing products of such substances may substantially reduce the risk of cardiovascular disease in the population."⁴

In the very first sentence of the reference, WESTRATE et al teaches the current state of the art (as of May 1998): "It is well established that linoleic acid lowers blood cholesterol concentrations compared to other more saturated types of fatty acids or carbohydrates." The Examiner notes that the Applicants used lineolic acid in their examples.

KANTHA explores the dietary effects of fish oils on human health. KANTHA teaches that a diet rich in omega-3 fatty acids significantly reduces plasma cholesterol and triglyceride levels, improves fat tolerance, prolongs bleeding times, reduces platelet counts, and decreases platelet adhesiveness.

⁴ See *Conclusion* on p334.

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Instant claims differ from the prior art in claiming a broader scope of conjugated fatty acids.

It would have been obvious to one skilled in the art at the time of invention to prepare at least one phytosterol ester of a conjugated fatty acid obtained from fish oils because KANTHA teaches that a diet rich in omega-3 fatty acids significantly reduces plasma cholesterol and triglyceride levels, improves fat tolerance, prolongs bleeding times, reduces platelet counts, and decreases platelet adhesiveness.

One skilled in the art would have been motivated to prepare a method of reducing serum cholesterol content in a mammal said method comprising providing a hypocholesteremic preparation comprising at least one phytosterol ester of a conjugated fatty acid because the prior art of KANTHA and WESTRATE et al teach that fish oils lower serum cholesterol levels and that esters from sitosterol, campesterol and stigmasterol is as effective as a margarine with sitostanol-ester in lowering blood total- and LDL-cholesterol levels. WESTRATE et al specifically teaches that it is well established that linoleic acid lowers blood cholesterol concentrations compared to other more saturated types of fatty acids or carbohydrates.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Examiner's Notes

The Examiner notes that the preferred fatty acid is conjugated linoleic acid (CLA) or conjugated fish fatty acids. See lines 10-17 of page 4 in the Specification.

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Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday, April 10, 2005